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MAILED #18

JAN 05 2004

REEXAM UNIT

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 6,344,053 was filed on November 26, 2003, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, S8 Over-the-Wire System (Driver® Stent Delivery System), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. It is noted that applications for patent term extension for U.S. Patent Nos. 5,292,331, 5,800,509, 5,836,965, 5,879,382, 5,891,190, 6,159,229, 6,309,402 and 6,344,053 were filed based upon the regulatory review period of the same medical device, and that a single patent would be required to be elected for extension.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Michael J. Jaro, Esq.
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